

308 Building/2A
May 13, 2002



Document Processing Desk - 6(a)(2)
Office of Pesticide Programs - 7504C
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

RE: FIFRA § 6(a)(2) Report
Vikane* Gas Fumigant
EPA Registration Number: 62719-4
Active Ingredient: Sulfuryl Fluoride
CAS Registry Number: 002699-79-8
DERBI Number: 104794
State: HI
Severity Category: H-C

Dow AgroSciences submits the following information in response to its understanding of the U.S. Environmental Protection Agency's interpretation of FIFRA § 6(a)(2). However, Dow AgroSciences has not concluded that this information regards an "unreasonable adverse effect on the environment" or that it is reportable under FIFRA § 6(a)(2).

Dow AgroSciences received the enclosed information regarding alleged human exposure.

It is important to note that the Vikane Gas Fumigant label requires the introduction of chloropicrin to the structure prior to fumigation at a rate of one ounce per 10,000-15,000 feet (17-25 ppm) to serve as a warning agent. This warning agent causes smarting of eyes, tearing, throat and nose irritation, and a disagreeable pungent odor at very low concentrations (ca. 0.3 ppm).

The Vikane Gas Fumigant label states the following: "When fumigating, observe local, state and federal rules and regulations including such things as use of chloropicrin, clearing devices, positive-pressure self contained breathing apparatus, security requirements, and placement of warning signs:... Extremely Hazardous Liquid and Vapor Under Pressure, Inhalation of Vapors may be Fatal." Under the "Preparation for Fumigation" section of the label, the use directions for structural fumigation state "Remove from the structure to be fumigated all persons, domestic animals, pets - including fish and desirable growing plants." Also, under the Aeration and Reentry section of the label, use directions state "... treated area must be aerated until the level of sulfuryl fluoride is 5 ppm or less, as measured by a detection device with sufficient sensitivity such as an INTERSCAN or MIRAN gas analyzer." Within this section of the label it further states "Do not reoccupy fumigation site, i.e. building, ship, vehicle or chamber, nor move vehicle until aeration is complete."

If you wish to discuss this matter further, please call us.

Regards,

Handwritten signature of Shannon Bass in black ink.

Shannon Bass
EH&S Global Product Leader
(317) 337-4983

Prepared by:

Handwritten signature of Stacey Fruits in black ink.

Stacey Fruits
Product Stewardship Administrator
(317) 337-4577

*Trademark of Dow AgroSciences

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area. Page# 1 of 3

Personal privacy

Row 1	Reporter Name [Redacted]	Submission date.	Contact person (if different than reporter)	Internal ID 1-3803101
Administrative Data	Address [Redacted]		Address	
	Phone # [Redacted]		Phone #	
	Incident Status: <i>New</i>	Location and date of incident <i>Haleiwa Hawaii 4/11/02</i>	Date registrant became aware of incident. <i>4/25/02</i>	Was incident part of larger study? <i>No</i>
Row 2	EPA Registration # (Product 1) <i>62719-4</i>	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
Pesticide(s) Involved	A.I. (s) <i>Sulfuryl Fluoride</i>	A.I. (s)	A.I. (s)	
	Product 1 name <i>Vikane</i>	Product 2 Name	Product 3 Name	
	Exposed to concentrate prior to dilution? <i>NA</i>	Exposed to concentrate prior to dilution?	Exposed to concentrate prior to dilution?	
	Formulation	Formulation	Formulation	
	Evidence label directions were not followed? <i>No</i> Intentional misuse? <i>No</i>		Incident site: (examples include home, yard, school, industrial, nursery/greenhouse, surface water, commercial turf, building/office, forest/ woods, agricultural (specify crop) right-of-way (rail, utility, highway)). <i>Own Residence</i>	
Applicator certified PCO? <i>Not applicable</i>		Situation (act of using product): (examples include mixing/loading, reentry, application, transportation, repair/maintenance of application equipment, manufacturing/ formulating). <i>Re-entry</i>		
How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff) <i>See Incident Description</i>				

DERBI: 104794
 Report: Yes No
 If no, Why: _____
 Date: 4/25/02
 SC HC

Brief description of incident circumstances.

*4/25/02 4:04:23 PM Vikane
Chloropicrin*

Caller says he was exposed to product two weeks ago (04/11) after home was tented, treated with Vikane and Chloropicrin. Says he waited 8 hours after home was cleared for entry before actually entering. Later that night, caller says he started seeing light flashes and hearing things. Says he left home that night, was disoriented and still suffered from Sx (flashing lights, hearing things). Was seen by pMD next day (04/12), had CXR, labs done –unspecified test of liver function was 10pts higher than prev. physical (done 2-3 weeks prior). CXR normal. Says he started developing pain in left arm, legs and abdomen. Says he has increasingly developed a loss of use or control of his hands and fingers. Was seen again by pMD last week (04/19), labs, CXR all normal. Was faxed info. from Co. (DowAgro). Says Sx still unresolved today, is calling IPC now as he just noted IPC's number on MSDS.

Referred caller to Tox Staff for further information.

*4/25/02 4:45:11 PM small amount of eye burning , light flashes in eyes, watching TV thought he heard voices when TV turned off, thought they were coming from a fan that was on. Feels very lethargic from time to time over the past 2 weeks. while driving gets sleepy sometimes, Sunday 14th right arm felt weak and he experienced tremors. On Tues night started to feel better mentally, couldn't do math calculations, had trouble balancing,
He was calling just to get information about product.*

Rec: Illness described is not indicative nor is it consistent with Vikane or chloropicrin toxicity. Medical complications would not be expected after a home was re-entered 8 hours after being cleared for re-entry by the PCO.

Should follow up with MD.

Voluntary Industry Reporting Form for 6(a)(2) Incident Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area. Page# 3 of 3

Demographic information: Age: <i>Unknown Adult (18-64)</i> Sex: <i>Male</i> Occupation (if relevant)	Exposure route: <i>Inhalation</i>	Was adverse effect result of suicide/homicide or attempted suicide/homicide? <i>No</i>	Was protective clothing worn (specify)? <i>Not applicable</i>
If female, pregnant? <i>Did not query</i>	Was exposure occupational? <i>No</i> If yes, days lost due to illness:	Time between exposure and onset of symptoms: <i>See Symptoms</i>	
Type of medical care sought: (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient). <i>On-site</i>	List signs/symptoms/adverse effects <i>Irritation/pain - Unable to determine , Drowsiness/Lethargy - Unable to determine , arm feels weak, tremors, Unable to determine Confusion - Unable to determine ,</i>		If lab tests were performed, list test names and results (If available, submit reports)
Exposure data: Amount of pesticide: Exposure duration: Weight:			
Human severity category: <i>HC</i>			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

These signs and symptoms are inconsistent with any adverse effects typically expected with Vikane. Considering the known toxicology profile and the circumstances described in this incident, these effects are inconsistent with the suspected or alleged exposure. Re-entry into a treated dwelling is not permitted until Vikane levels drop below 5 ppm, a level well below threshold for toxicity.

Internal ID #
1-3803101

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RE: FIFRA § 6(a)(2) Report
Vikane* Gas Fumigant
EPA Registration Number: 62719-4
Active Ingredient: Sulfuryl Fluoride
CAS Registry Number: 002699-79-8
DERBI Number: 104804
State: FL
Severity Category: H-C

Dow AgroSciences submits the following information in response to its understanding of the U.S. Environmental Protection Agency's interpretation of FIFRA § 6(a)(2). However, Dow AgroSciences has not concluded that this information regards an "unreasonable adverse effect on the environment" or that it is reportable under FIFRA § 6(a)(2).

Dow AgroSciences received the enclosed information regarding alleged human exposure.

It is important to note that the Vikane Gas Fumigant label requires the introduction of chloropicrin to the structure prior to fumigation at a rate of one ounce per 10,000-15,000 feet (17-25 ppm) to serve as a warning agent. This warning agent causes smarting of eyes, tearing, throat and nose irritation, and a disagreeable pungent odor at very low concentrations (ca. 0.3 ppm).

The Vikane Gas Fumigant label states the following: "When fumigating, observe local, state and federal rules and regulations including such things as use of chloropicrin, clearing devices, positive-pressure self contained breathing apparatus, security requirements, and placement of warning signs:... Extremely Hazardous Liquid and Vapor Under Pressure, Inhalation of Vapors may be Fatal." Under the "Preparation for Fumigation" section of the label, the use directions for structural fumigation state "Remove from the structure to be fumigated all persons, domestic animals, pets - including fish and desirable growing plants." Also, under the Aeration and Reentry section of the label, use directions state "... treated area must be aerated until the level of sulfuryl fluoride is 5 ppm or less, as measured by a detection device with sufficient sensitivity such as an INTERSCAN or MIRAN gas analyzer." Within this section of the label it further states "Do not reoccupy fumigation site, i.e. building, ship, vehicle or chamber, nor move vehicle until aeration is complete."

If you wish to discuss this matter further, please call us.

Regards,


Shannon Bass
EH&S Global Product Leader
(317) 337-4983

Prepared by:


Stacey Fruits
Product Stewardship Administrator
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Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area. Page# 1 of 3

Personal privacy

Row 1 Administrative Data	Reporter Name	Submission date.	Contact person (if different than reporter)	Internal ID <i>1-3907942</i>
	Address <i>Florida</i>		Address	
	Phone #		Phone #	
	Incident Status: <i>New</i>	Location and date of incident <i>Florida 3/3/02</i>	Date registrant became aware of incident. <i>5/3/02</i>	Was incident part of larger study? <i>No</i>
Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) <i>62719-4</i>	EPA Registration # (Product 2)	EPA Registration # (Product 3)	
	A.I. (s) <i>Sulfuryl Fluoride</i>	A.I. (s)	A.I. (s)	
	Product 1 name <i>Vikane</i>	Product 2 Name	Product 3 Name	
	Exposed to concentrate prior to dilution? <i>No</i>	Exposed to concentrate prior to dilution?	Exposed to concentrate prior to dilution?	
	Formulation	Formulation	Formulation	
Row 3 Incident Circumstances	Evidence label directions were not followed? <i>No</i> Intentional misuse? <i>No</i>	Incident site: (examples include home, yard, school, industrial, nursery/greenhouse, surface water, commercial turf, building/office, forest/ woods, agricultural (specify crop) right-of-way (rail, utility, highway)). <i>Other Residence</i>	Situation (act of using product): (examples include mixing/loading, reentry, application, transportation, repair/maintenance of application equipment, manufacturing/ formulating). <i>Re-entry</i>	
	Applicator certified PCO? <i>Not applicable</i>			
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff) <i>See Incident Description</i>			

DERBI: 104804
Report: Yes No
If no, Why:
Date: 5/10/02

Brief description of incident circumstances.

5/3/02 9:01:56 AM Mother calling about 44yr old daughter who she believes was exposed to Vikane 2 months ago and has been ill ever since.

She is a housekeeper at a private residence. 2 months ago the house was treated with Vikane. There was a sign on the home door stating it was safe to enter. Pt was the first one to enter. There was no information on the door about contacting the PCO if questions/concerns/ odor present. Pt went in to clean the house. She smelled something, and opened windows. Was there 5 hours. After leaving house, speech became very slow and garbled. Was brought to ED by husband. In ED, face was red. Nothing was done at hospital. Next day, speech was very fast.

Went to MD. Went to ED x 3 that week. No one could find out what was wrong.

Then stomach kept "swirling", then had blood in stool.

She has also had problems finding the right words and saying them properly.

All the Dr.s say either/and: sx cannot be from Vikane or they don't want to get involved because there may be a lawsuit. (They have not contacted an attorney).

Currently, her voice continues to be raspy and she is having dysarticulation problems.

Caller is distraught because she is trying to get help for her daughter. I said this must be very difficult for them and it doesn't make sense that the doctors they have seen don't eval and test her. She was glad that I was sensitive to their worry about pt's welfare.

Caller has information on Vikane and she states the list of sx described are what her daughter has.

She has also talked to the S. Florida Poison Center.

Has name of a Neuro/psychologist.

A: Vikane unlikely source of sx. Daughter obviously has sx that need to be eval. Suggested they need to have a MD who will coordinate evaluations and testing. If she wants to pursue ruling out Vikane, try calling the Fl Poison Center and ask if they have a tox clinic or can recd a MD toxicologist for eval. Case # given. CB prn or have MD cb prn. Told caller we would CB next week. consulted with JR. JG notified via email.

5/3/02 12:32:50 PM reviewed case.

Voluntary Industry Reporting Form for 6(a)(2) Incident Information Involving Humans

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area. Page# 3 of 3

Demographic information: Age: 44 Years Sex: Female Occupation (if relevant)	Exposure route: Unknown	Was adverse effect result of suicide/homicide or attempted suicide/homicide? No	Was protective clothing worn (specify)? Not applicable
If female, pregnant? Did not query	Was exposure occupational? No If yes, days lost due to illness:	Time between exposure and onset of symptoms: See Symptoms	
Type of medical care sought: (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient). HCF	List signs/symptoms/adverse effects Slurred speech - 6 hrs or less , dysarticulation, fast speech Unable to determine Erythema/Flushed - 6 hrs or less , Abdominal Pain - Unable to determine , Melena - Unable to determine , Respiratory irritation - 6 hrs or less , raspy voice Unable to determine Confusion - Unable to determine ,		If lab tests were performed, list test names and results (If available, submit reports)
Exposure data: Amount of pesticide: Exposure duration: Weight:			
Human severity category: HC			

This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)

Re-entry into a treated dwelling is not permitted until Vikane levels drop below 5 ppm, a level known to be well below the threshold for potential toxicity. Chloropicrin, a lacrimating warning agent, is also used with Vikane and may produce eye irritation and upper respiratory irritation. Chloropicrin would typically have dissipated by the time the tenants returned to the residence. The signs and symptoms reported are not consistent with the toxicological profile of either Vikane or chloropicrin.

Internal ID #
1-3907942